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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

HIKMA PHARMACEUTICALS USA INC.,

Plaintiff,

v.

AMARIN PHARMA, INC., AMARIN
PHARMACEUTICALS IRELAND
LIMITED, AND AMARIN CORPORATION
PLC,

Defendants.

Civil Action No. 23-01016 (ZNQ)(TJB)

(Filed Electronically)

DEFENDANTS' ANSWER AND AFFIRMATIVE DEFENSES TO THE COMPLAINT

Defendants Amarin Pharma, Inc., Amarin Pharmaceuticals Ireland Limited, and Amarin Corporation plc (collectively, "Amarin"), by and through their attorneys, hereby answer and assert defenses to the claims and allegations made by Hikma Pharmaceuticals USA Inc. ("Plaintiff" or "Hikma") in the Complaint, ECF No. 1, filed on February 21, 2023 (the "Complaint"). Amarin responds based upon its knowledge as to allegations pertaining to Amarin and upon information and belief as to allegations pertaining to all other matters.

Except as specifically admitted, each factual assertion by Plaintiff is denied. Although Amarin has re-produced below the Complaint's headings and subheadings, Amarin further denies each and every factual allegation contained in the Complaint's headings or subheadings. Numbered paragraphs below correspond to the like-numbered paragraphs in the Complaint.

INTRODUCTION

1. Paragraph 1 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 1.

2. Amarin admits that Vascepa® (icosapent ethyl) is a prescription medication approved by the FDA to treat severe hypertriglyceridemia in adults and as an adjunct to maximally tolerated statin therapy to reduce the risk of cardiovascular events in certain adult patient groups. Amarin admits that Vascepa is Amarin's only product in the United States (the product is sold as Vazkepa® in Europe). Amarin denies the remaining allegations in Paragraph 2.

3. With respect to the allegations in the first sentence of Paragraph 3, Amarin refers to Amarin Corporation plc's Form 10-K filings for a complete and accurate statement of its revenues by year and denies Plaintiff's allegations to the extent they are inconsistent with those filings. The remaining allegations in Paragraph 3 purport to characterize the content of the cited press release. Amarin refers to that document for a complete and accurate statement of its contents, and denies the allegations to the extent they are inconsistent with or characterize the document. Amarin otherwise denies the allegations in Paragraph 3.

4. The allegations in Paragraph 4 purport to characterize the content of the cited document. Amarin refers to that document for a complete and accurate statement of its contents, and denies the allegations to the extent they are inconsistent with or characterize the document.

5. With respect to the first three sentences in Paragraph 5, Amarin admits that Vascepa is Amarin's only product in the United States (the product is sold as Vazkepa in Europe). The allegations in Paragraph 5 also purport to characterize the content of the cited documents. Amarin refers to those documents for a complete and accurate statement of their contents, and denies the allegations to the extent they are inconsistent with or characterize the documents. In particular, the quote in the first cited document is incomplete, as is the statement in the second cited document. Amarin otherwise denies the allegations in Paragraph 5.

6. Amarin denies the allegations in Paragraph 6.

7. Paragraph 7 characterizes Plaintiff's claims and states legal conclusions, for which no response is required. To the extent a response is required, Amarin denies the allegations in Paragraph 7. Paragraph 7 also purports to characterize Amarin's supply agreements. Amarin refers to those agreements for a complete and accurate statement of their contents. Amarin denies the remaining allegations in Paragraph 7.

8. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 8 relating to industry practice concerning the number of API suppliers, and denies those allegations on that basis. Amarin denies the remaining allegations in Paragraph 8.

9. Amarin admits that in 2012, the FDA approved Vascepa as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe hypertriglyceridemia. Amarin admits that Hikma provided a Paragraph IV notice to Amarin in September 2016 and admits that Amarin sued Hikma and other generic manufacturers for patent infringement. Amarin admits that under FDA regulations, the filing of those patent infringement suits triggered a stay on FDA approval of the generic applications. Amarin admits that in 2019, the FDA approved a second indication for Vascepa for use as an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial

infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated TG levels and established cardiovascular disease or diabetes mellitus and two or more additional risk factors for cardiovascular disease. Amarin denies the remaining allegations in Paragraph 9.

10. Amarin admits that the United States District Court for the District of Nevada issued an opinion on March 30, 2020 finding Amarin's patents invalid due to obviousness. The remaining allegations are a reference to and characterization of the opinion. Amarin refers to the opinion in *Amarin Pharm. Inc. v. Hikma Pharms. USA Inc.*, 449 F. Supp. 3d 967 (D. Nev. Mar. 30, 2020) for a complete and accurate statement of its contents and denies the allegations to the extent they are inconsistent with or characterize the opinion.

11. Amarin admits, on information and belief, the allegations in the first two sentences of Paragraph 11. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the final sentence of Paragraph 11 and denies the allegations on that basis.

12. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the first two sentences of Paragraph 12 and denies the allegations on that basis. Amarin denies the remaining allegations in Paragraph 12.

13. The allegations in Paragraph 13 are a characterization of and reference to the cited document. Amarin refers to that document for a complete and accurate statement of its contents and denies Plaintiff's allegations to the extent they are inconsistent with the cited document. Amarin otherwise denies the allegations in Paragraph 13.

14. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations regarding Hikma's communications or contracts with API suppliers, and denies the allegations on that basis. Amarin denies the remaining allegations in Paragraph 14.

15. Amarin admits, on information and belief, that Hikma launched in November 2020. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in the first sentence of Paragraph 15, and denies the allegations on that basis. The remaining allegations state legal conclusions for which no response is required. To the extent a response is required, Amarin denies the remaining allegations in Paragraph 15.

16. The allegations in Paragraph 16 state legal conclusions for which no response is required. To the extent a response is required, Amarin denies the allegations in Paragraph 16.

THE PARTIES

17. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 17.

18. Amarin admits the allegations in Paragraph 18.

19. Amarin admits the allegations in Paragraph 19.

20. Amarin admits Amarin Corporation plc is a company incorporated under the laws of England and Wales with principle executive offices located in Dublin, Ireland. Amarin denies the remaining allegations in Paragraph 20.

JURISDICTION AND VENUE

21. Paragraph 21 contains no factual allegations and therefore does not require a response. To the extent a response is required, Amarin denies that Plaintiff is entitled to any relief.

22. Amarin admits that its products are marketed and sold in the United States. Amarin admits that drug wholesalers located in the United States purchase Vascepa. Amarin admits that patients in the United States can purchase Vascepa through pharmacies and other intermediaries. The remaining allegations in Paragraph 16 reflect legal conclusions, for which no response is required. To the extent a response is required, Amarin denies the remaining allegations in Paragraph 22.

23. Amarin admits that Amarin Pharma, Inc. may be found in, transacts business in, and is headquartered in New Jersey. The remainder of Paragraph 23 purports to state a legal conclusion to which no response is required.

24. Paragraph 24 states a legal conclusion to which no response is required.

25. Paragraph 25 states a legal conclusion to which no response is required.

26. Paragraph 26 states a legal conclusion to which no response is required.

27. Paragraph 27, in part, states legal conclusions regarding venue to which no response is required. Amarin denies the remaining allegations in Paragraph 27.

STATEMENT OF FACTS

A. Regulatory Framework

28. The first two sentences of Paragraph 28 purport to describe requirements of the Hatch-Waxman Act. Amarin refers to the text of the Act for a complete and accurate statement of its provisions and denies Plaintiff's allegations in Paragraph 28 to the extent they are inconsistent with the text of the Act. Amarin lacks knowledge or information sufficient to form a belief as to the overarching purpose of the Hatch-Waxman Act, and denies the remaining allegations in Paragraph 28 on that basis.

29. Paragraph 29 purports to describe provisions of the Food, Drug, and Cosmetic Act. Amarin refers to the text of the Food, Drug, and Cosmetic Act for a complete and accurate statement of its provisions and denies Plaintiff's allegations in Paragraph 29 to the extent they are inconsistent with the text of the Act.

30. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 30 and denies the allegations on that basis.

31. Paragraph 31 purports to describe requirements of the Hatch-Waxman Act. Amarin refers to the text of the Hatch-Waxman Act for a complete and accurate statement of its provisions and denies Plaintiff's allegations in Paragraph 31 to the extent they are inconsistent with the text of the Act.

32. Paragraph 32 purports to describe requirements of the Hatch-Waxman Act. Amarin refers to the text of the Hatch-Waxman Act for a complete and accurate statement of its provisions and denies Plaintiff's allegations in Paragraph 32 to the extent they are inconsistent with the text of the Act.

33. Paragraph 33 purports to describe requirements of the Hatch-Waxman Act and FDA practice. Amarin refers to the text of the Hatch-Waxman Act for a complete and accurate statement of its provisions and denies Plaintiff's allegations in Paragraph 33 to the extent they are inconsistent with the text of the Act or FDA practice.

34. Paragraph 34 purports to describe requirements of the Hatch-Waxman Act. Amarin refers to the text of the Hatch-Waxman Act for a complete and accurate statement of its provisions and denies Plaintiff's allegations in Paragraph 34 to the extent they are inconsistent with the text of the Act.

35. Paragraph 35 purports to describe requirements of the Hatch-Waxman Act. Amarin refers to the text of the Hatch-Waxman Act for a complete and accurate statement of its provisions and denies Plaintiff's allegations in Paragraph 35 to the extent they are inconsistent with the text of the Act.

36. Paragraph 36 purports to describe requirements of the Hatch-Waxman Act. Amarin refers to the text of the Hatch-Waxman Act for a complete and accurate statement of its provisions and denies Plaintiff's allegations in Paragraph 36 to the extent they are inconsistent with the text of the Act.

37. The first sentence of Paragraph 37 purports to describe provisions of the Hatch-Waxman Act. Amarin refers to the text of the Hatch-Waxman Act for a complete and accurate statement of its provisions and denies Plaintiff's allegations in the first sentence of Paragraph 37 to the extent they are inconsistent with the text of the Act. The second sentence of Paragraph 37 purports to characterize FDA regulations. Amarin refers to the text of the cited FDA regulations for a complete and accurate statement of their provisions and denies Plaintiff's allegations in the second sentence of Paragraph 37 to the extent they are inconsistent with the text of those regulations. The third sentence of Paragraph 37 states legal conclusions and cites sources that purportedly support those conclusions, and therefore does not require a response.

38. Paragraph 38 contains no factual allegations and therefore does not require a response. To the extent a response is required, Paragraph 38 purports to describe requirements of the Hatch-Waxman Act. Amarin refers to the text of the Hatch-Waxman Act for a complete and accurate statement of its provisions and denies Plaintiff's allegations in Paragraph 38 to the extent they are inconsistent with the text of the Act.

B. Supply and Use of API

39. On information and belief, Amarin admits the allegations in Paragraph 39.

40. Amarin admits, on information and belief, the allegations in Paragraph 40.

41. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 41 and denies the allegations on that basis.

42. Paragraph 42 purports to describe FDA regulatory requirements relating to Drug Master Files (DMF). Amarin denies the allegations in Paragraph 42 to the extent the allegations are contrary to FDA regulations and practice.

43. Paragraph 43 purports to describe FDA regulatory requirements relating to DMFs. Amarin denies the allegations in Paragraph 43 to the extent the allegations are contrary to FDA regulations and practice. Indeed, as the Third Circuit has observed, “[a] manufacturer need not partner with a supplier with an active DMF during its development of an ANDA, and sometimes a drug applicant may choose to not reference a DMF in its ANDA filing at all.” *See Fresenius Kabi USA, LLC v. Par Sterile Prods., LLC*, 841 F. App’x 399, 404 n.12 (3d Cir. 2021). Amarin denies the remaining allegations in Paragraph 43.

44. Paragraph 44 purports to describe FDA regulatory requirements relating to DMFs. Amarin denies the allegations in Paragraph 44 to the extent the allegations are contrary to FDA regulations and practice. Indeed, as the Third Circuit has observed, “[a] manufacturer need not partner with a supplier with an active DMF during its development of an ANDA, and sometimes a drug applicant may choose to not reference a DMF in its ANDA filing at all.” *See Fresenius Kabi USA, LLC v. Par Sterile Prods., LLC*, 841 F. App’x 399, 404 n.12 (3d Cir. 2021).

45. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 45 and denies the allegations on that basis.

46. Amarin admits, on information and belief, that there can be significant costs involved in qualifying an API supplier. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 46 regarding industry practices concerning the number of API suppliers and denies the allegations on that basis.

47. Amarin admits, on information and belief, that generic versions of brand drugs typically contain the same active ingredient(s) as the brand name drug. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 47 and denies the allegations on that basis.

48. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the second sentence of Paragraph 48 and denies the allegations on that basis. Amarin also denies the allegations in Paragraph 48 as hypothetical in nature to the extent they purport to be characterizations of the marketplace conditions in this case. The remaining allegations in Paragraph 48 reflect legal conclusions, for which no response is required.

49. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 49 and denies the allegations on that basis. Amarin also denies the allegations in Paragraph 49 as hypothetical in nature to the extent they purport to be characterizations of the marketplace conditions in this case.

C. Amarin's Vascepa® Product

50. Amarin admits the allegations in Paragraph 50.

51. Amarin admits the allegations in Paragraph 51.

52. Since Vascepa's first approval in 2012, Amarin has listed certain patents in connection with Vascepa in the Orange Book. Amarin refers to the Orange Book and the listed patents for their contents.

53. Since Vascepa's first approval in 2012, Amarin has listed certain patents in connection with Vascepa in the Orange Book. Amarin refers to the Orange Book and the listed patents for their contents.

D. Amarin Enters Exclusive Supply Agreements Designed to Harm Competition

54. Amarin admits that at times, it has had contractual arrangements with the companies listed in Paragraph 54 (or their predecessors). Amarin otherwise denies the allegations in Paragraph 54.

55. Amarin admits that it entered into an icosapent ethyl API supply agreement with Nisshin in November 2010. Amarin further admits that it included Nisshin as its API supplier in Amarin's NDA and that it initially purchased its icosapent ethyl API supply for marketed Vascepa from Nisshin. Paragraph 55 otherwise purports to characterize the terms of a contract. Amarin refers to the contract for a complete and accurate statement of its contents and denies Plaintiff's allegations to the extent they are inconsistent with the text of the contract. Amarin otherwise denies the allegations in Paragraph 55.

56. Paragraph 56 purports to characterize terms of a contract and information in Amarin Corporation plc's Form 10-Q filing. Amarin refers to the contract and the filing for a complete and accurate statement of their contents and denies Plaintiff's allegations to the extent they are inconsistent with those documents and to the extent they characterize the information therein.

57. With respect to the first sentence, Amarin admits that it entered into a contract with Equateq Limited in 2011 but otherwise denies this sentence. Paragraph 57 purports to characterize terms of a contract and information in Amarin Corporation plc's Form 10-Q filing. Amarin refers to the contract and the filing for a complete and accurate statement of their contents and denies Plaintiff's allegations to the extent they are inconsistent with those documents and to the extent they characterize the information therein. Amarin admits, on information and belief, the final sentence of Paragraph 57. Amarin otherwise denies the allegations in Paragraph 57.

58. Paragraph 58 purports to characterize terms of a contract and statements in a press release. Amarin refers to the contract and the press release for a complete and accurate statement of their contents and denies Plaintiff's allegations to the extent they are inconsistent with the text of the documents. Amarin otherwise denies the allegations in Paragraph 58.

59. Amarin admits its 2012 FDA approval included the approval of Nisshin as an API supplier and that Amarin, in line with FDA regulations, filed supplemental new drug applications (sNDA) for approval of additional suppliers. Amarin denies the remaining allegations in Paragraph 59.

60. Amarin admits that, at times, it has had contractual arrangements with Chemport and that it submitted an sNDA to the FDA on or about December 2012 seeking approval for Chemport, Inc. as an additional API supplier. The remaining allegations in Paragraph 60 purport to characterize the content of the cited document. Amarin refers to that document for a complete and accurate statement of its contents, and denies the allegations to the extent they are inconsistent with or characterize the document. Amarin otherwise denies the allegations in Paragraph 60.

61. The allegations in Paragraph 61 purport to characterize the content of the cited documents. Amarin refers to those documents for a complete and accurate statement of their

contents, and denies the allegations to the extent they are inconsistent with or characterize the documents. Amarin denies the remaining allegations in Paragraph 61.

62. Amarin admits that, at times, it has had contractual arrangements with BASF, and that it submitted an sNDA to the FDA on or about January 2013 seeking approval for BASF as an additional API supplier. The remaining allegations in Paragraph 62 purport to characterize the content of the cited documents. Amarin refers to those documents for a complete and accurate statement of their contents, and denies the allegations to the extent they are inconsistent with or characterize the documents. Amarin denies the remaining allegations in Paragraph 62

63. Amarin admits it submitted an sNDA to the FDA on or about August 2013 seeking approval for Novasep as an additional API supplier. The second sentence of Paragraph 63 quotes from an uncited source. Amarin refers to that source for a complete and accurate statement of its contents, and denies the allegations to the extent they are inconsistent with or characterize the document. Amarin denies the remaining allegations in Paragraph 63, including in the chart. For example, the information in the chart is inconsistent with Plaintiff's own allegations. *Cf.* Compl., ¶ 60 (listing FDA filing date for Chemport as December 2012) and chart (listing FDA filing date for Chemport as April 2013).

64. Amarin denies the allegations in Paragraph 64.

65. Paragraph 65 purports to characterize terms of contracts. Amarin refers to the contracts for a complete and accurate statement of their contents and denies Plaintiff's allegations to the extent they are inconsistent with the text of the contracts. Amarin otherwise denies the allegations in Paragraph 65.

66. Paragraph 66 purports, in part, to characterize terms of contracts and a press release. Amarin refers to the contracts and the press release for a complete and accurate statement of their contents and denies Plaintiff's allegations to the extent they are inconsistent with the text of the contracts and the press release. Amarin denies the remaining allegations in Paragraph 66.

67. Paragraph 67 purports, in part, to characterize terms of contracts. Amarin refers to the contracts for a complete and accurate statement of their contents and denies Plaintiff's allegations to the extent they are inconsistent with the text of the contracts. Amarin denies the remaining allegations in Paragraph 67.

68. The allegations in Paragraph 68 are a characterization of and reference to the cited documents. Amarin refers to the cited sources for a complete and accurate statement of their contents and denies Plaintiff's allegations to the extent they are inconsistent with the cited sources and to the extent they characterize the information therein. In particular, the second cited press release has nothing to do with the topic of the paragraph and does not contain the term "barriers to entry." Amarin denies the remaining allegations in Paragraph 68.

69. Amarin denies the allegations in Paragraph 69, including the allegations in the graphic.

70. The allegations in Paragraph 70 are, in part, a characterization of and reference to the cited documents. Amarin refers to those documents for a complete and accurate statement of their contents and denies Plaintiff's allegations to the extent they are inconsistent with the cited documents. Amarin denies the remaining allegations in Paragraph 70, including the allegations in the graphic.

71. Amarin denies the allegations in Paragraph 71.

72. The allegations in Paragraph 72 are, in part, a characterization of and reference to the cited document. Amarin refers to that document for a complete and accurate statement of its contents and denies Plaintiff's allegations to the extent they are inconsistent with the cited document. Amarin denies the remaining allegations in Paragraph 72.

E. Generic Manufacturers Apply for FDA Approval to Compete with Amarin

73. Amarin admits, on information and belief, that Roxane, DRL, Teva, and Apotex filed applications with the FDA in 2016. Amarin lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 73, and denies the allegations on that basis.

74. Amarin admits, on information and belief, the allegations in Paragraph 74.

F. Amarin's First Round of Unsuccessful Patent Litigation

75. Amarin admits that it filed a patent infringement lawsuit against Hikma in the District of Nevada on October 31, 2016, asserting that Hikma's ANDA product would infringe certain patents listed for Vascepa. Amarin refers to the complaint, asserted patents, and Orange Book for their contents.

76. Amarin refers to the cited opinion for a complete and accurate statement of its contents and denies Plaintiff's allegations to the extent they are inconsistent with that source. The allegations in Paragraph 76 otherwise state legal conclusions for which no response is required.

77. Amarin refers to the cited opinion for a complete and accurate statement of its contents and denies Plaintiff's allegations to the extent they are inconsistent with that source.

78. Amarin admits the allegation in the first sentence of Paragraph 78. Amarin admits that the Federal Circuit affirmed the Nevada court's ruling, and otherwise refers to the cited opinion for a complete and accurate statement of its contents and denies Plaintiff's allegations to the extent they are inconsistent with that source.

79. Amarin admits its request for rehearing by the Federal Circuit was denied and that it petitioned for a writ of certiorari from the Supreme Court which was denied on June 21, 2021. Amarin otherwise denies the allegations in Paragraph 79.

G. Hikma's API Supply-Constraint Shock

80. Amarin denies the allegations in Paragraph 80.

81. Amarin lacks knowledge or information sufficient to form a belief as to the business discussions between Hikma and API suppliers, and denies the allegations on that basis. Amarin denies the remaining allegations in Paragraph 81.

82. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations Paragraph 82, and denies the allegations on that basis.

83. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations Paragraph 83, and denies the allegations on that basis.

84. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations Paragraph 84, and denies the allegations on that basis.

85. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations Paragraph 85, and denies the allegations on that basis.

86. Amarin denies the allegations in Paragraph 86.

87. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations Paragraph 87, and denies the allegations on that basis.

88. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations regarding supplier pricing and Hikma's launch quantities, and denies those allegations on that basis. Amarin denies the remaining allegations in Paragraph 88.

89. Amarin admits, on information and belief, that Hikma received FDA approval in May 2020 and launched in November 2020. Amarin denies the remaining allegations in Paragraph 89.

90. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 90 regarding Hikma's price and denies the allegations on that basis. Amarin otherwise denies the allegations in Paragraph 90.

91. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations Paragraph 91 and the accompanying graphic, and denies the allegations on that basis. Amarin also denies the allegations in Paragraph 91 and the accompanying graphic as hypothetical in nature to the extent they purport to be characterizations of the marketplace conditions in this case.

92. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations Paragraph 92 and the accompanying graphic, and denies the allegations on that basis. Amarin also denies the allegations in Paragraph 92 and the accompanying graphic as hypothetical in nature to the extent they purport to be characterizations of the marketplace conditions in this case.

93. Amarin denies the allegations in Paragraph 93.

94. Amarin denies the first sentence in Paragraph 94. With respect to the second sentence, Amarin points to the identified company's formulary for a true and correct copy of its contents and otherwise denies Paragraph 94 to the extent it is inconsistent with the contents therein.

95. Amarin refers to the cited press release for a complete and accurate statement of its contents and denies Plaintiff's allegations to the extent they are inconsistent with that source.

96. Amarin refers to the cited earnings call transcript for a complete and accurate statement of its contents and denies Plaintiff's allegations to the extent they are inconsistent with that source. Amarin denies the remaining allegations in Paragraph 96.

97. Amarin denies the allegations in Paragraph 97 and the accompanying graphic. Amarin also denies the allegations in Paragraph 97 and the accompanying graphic as hypothetical in nature to the extent they purport to be characterizations of the marketplace conditions in this case.

98. The allegations in the first sentence of Paragraph 98 reflect legal conclusions, for which no response is required. To the extent a response is required, Amarin denies the allegations in the first sentence of Paragraph 98. Amarin denies the remaining allegations in Paragraph 98.

99. The allegations in Paragraph 99 are a characterization of and reference to the cited document. Amarin refers to that document for a complete and accurate statement of its contents and denies Plaintiff's allegations to the extent they are inconsistent with the cited document. In addition, Paragraph 99 states a legal conclusion to which no response is required. To the extent a response is required, Amarin denies the remaining allegations in Paragraph 99.

100. Amarin denies the allegations in Paragraph 100.

101. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 101 and denies the allegations on that basis. Amarin also specifically denies the last phrase in Paragraph 101.

H. Amarin's Second Round of Meritless Patent Litigation

102. Amarin admits the allegations in the first sentence of Paragraph 102. The allegations in the second sentence of Paragraph 102 reflects legal conclusions, for which no response is required. To the extent a response is required, Amarin denies the allegations in the second sentence of Paragraph 102.

103. Amarin admits that on January 4, 2022, the court dismissed Amarin's complaint against Hikma and that Amarin has appealed this ruling. Amarin refers to the cited opinion and filing for a complete and accurate statement of their contents, and denies Plaintiff's allegations to the extent they are inconsistent with those sources and to the extent they characterize the information therein.

MONOPOLY POWER AND RELEVANT MARKETS

104. The allegations in Paragraph 104 reflect legal conclusions, for which no response is required. To the extent a response is required, Amarin denies the allegations in Paragraph 104.

105. The first sentence of Paragraph 105 states a legal conclusion to which no response is required. To the extent a response is required, Amarin denies the allegations in the first sentence of Paragraph 105. The second sentence purports to describe FDA practice, and Amarin denies the allegations in the second sentence of Paragraph 105 to the extent the allegations are contrary to FDA regulations and practice.

106. Paragraph 106 states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 106.

107. Amarin admits that the demand for Vascepa has increased over certain periods of time. Paragraph 107 otherwise characterizes Plaintiff's claims, states legal conclusions, and is hypothetical in nature, and therefore does not require a response. To the extent a response is required, Amarin denies the remaining allegations in Paragraph 107.

108. The first sentence of Paragraph 108 characterizes Plaintiff's claims, states legal conclusions, and is hypothetical in nature, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in the first sentence of Paragraph 108. Amarin denies the allegations in the second sentence of Paragraph 108.

109. The allegations in Paragraph 109 reflect legal conclusions, for which no response is required. To the extent a response is required, Amarin denies the allegations in Paragraph 109.

110. Amarin admits that Amarin has sold Vascepa at a price in excess of Amarin's marginal cost. The remaining allegations in Paragraph 110 reflect legal conclusions, for which no response is required. To the extent a response is required, Amarin denies the remaining allegations in Paragraph 110.

111. The allegations in Paragraph 111 reflect legal conclusions, for which no response is required. To the extent a response is required, Amarin denies the allegations in Paragraph 111.

112. The allegations in the first two sentences of Paragraph 112 reflect legal conclusions, for which no response is required. To the extent a response is required, Amarin denies the allegations in the first two sentences of Paragraph 112. With respect to the allegations in the final sentence of Paragraph 112, Amarin refers to the August 4, 2020 earnings call transcript for a complete and accurate statement of its contents and denies Plaintiff's allegations to the extent they are inconsistent with that source.

113. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations relating to the quantities of Hikma's launch in the second sentence of Paragraph 113 and denies the allegations on that basis. The remaining allegations in Paragraph 113 reflect legal conclusions, for which no response is required. To the extent a response is required, Amarin denies the remaining allegations in Paragraph 113.

114. The allegations in Paragraph 114 reflect legal conclusions, for which no response is required. To the extent a response is required, Amarin denies the allegations in Paragraph 114.

115. The allegations in Paragraph 115 reflect legal conclusions, for which no response is required. To the extent a response is required, Amarin denies the allegations in Paragraph 115.

116. Amarin admits that the demand for Vascepa has increased over certain periods of time. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations regarding the demand for Lovaza and generic omega-3-acid ethyl esters drug products in Paragraph 116, and denies those allegations on that basis. Amarin denies the remaining allegations in Paragraph 116. In particular, the allegations do not account for the net pricing of Vascepa.

117. Amarin denies the allegations in Paragraph 117.

118. Amarin denies the allegations in Paragraph 118.

119. Amarin admits that Vascepa is a prescription medicine and is not sold directly to consumers without a prescription. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 119 given the generality of the allegations, and denies the allegations on that basis.

120. The allegation in Paragraph 120 reflects legal conclusions, for which no response is required.

ANTITRUST IMPACT

121. Paragraph 121 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 121.

122. Amarin denies the allegations in Paragraph 122.

123. Paragraph 123 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 123. The allegations in Paragraph 123 are also a characterization of and reference to the cited document. Amarin refers to that document for a complete and accurate statement of its contents and denies Plaintiff's allegations to the extent they are inconsistent with the cited document. Amarin denies the remaining allegations in Paragraph 123.

124. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 124 and denies the allegations on that basis. Amarin specifically denies the allegations in the second sentence of Paragraph 124. Amarin also denies the allegations in Paragraph 124 as hypothetical in nature to the extent they purport to be characterizations of the marketplace conditions in this case. Amarin refers to the cited FTC study for complete and accurate statement of its contents and denies Plaintiff's allegations characterizing the results of the studies to the extent they are inconsistent with the text of the cited source.

125. Paragraph 125 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the

allegations in Paragraph 125. The allegations in Paragraph 125 are also a characterization of and reference to the cited documents. Amarin refers to those document for a complete and accurate statement of their contents and denies Plaintiff's allegations to the extent they are inconsistent with the cited documents. Amarin denies the remaining allegations in Paragraph 125.

126. Paragraph 126 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 126.

127. Paragraph 127 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 127.

128. Paragraph 128 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 128.

129. Paragraph 129 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 129.

AMARIN'S CONDUCT HAS NO LEGITIMATE BUSINESS PURPOSE

130. Amarin denies the allegations in Paragraph 130.

131. Amarin lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 131 relating to industry practice concerning the number of API suppliers, and denies those allegations on that basis. Amarin denies the remaining allegations in Paragraph 131.

132. Amarin denies the allegations in Paragraph 132.

133. The allegations in Paragraph 133 are a characterization of and reference to the cited documents. Amarin refers to those documents for a complete and accurate statement of their contents and denies Plaintiff's allegations to the extent they are inconsistent with the cited documents. Amarin denies the remaining allegations in Paragraph 133.

134. The allegations in Paragraph 134 are a characterization of and reference to the cited document. Amarin refers to that document for a complete and accurate statement of its contents and denies Plaintiff's allegations to the extent they are inconsistent with the cited document. Amarin denies the remaining allegations in Paragraph 134.

COUNT I
(Sherman Act Section I – Conspiracy)

135. Amarin incorporates its answers to Paragraphs 1 through 134 as though fully set forth herein.

136. Paragraph 136 states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 136.

137. Paragraph 137 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 137.

138. Paragraph 138 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 138.

139. Paragraph 139 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 139.

140. Paragraph 140 states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 140.

141. Paragraph 141 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 141.

142. Paragraph 142 states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 142. Amarin also denies that Plaintiff is entitled to any relief.

COUNT II
(Sherman Act Section 2 – Monopolization)

143. Amarin incorporates its answers to Paragraphs 1 through 142 as though fully set forth herein.

144. Paragraph 144 states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 144.

145. Paragraph 145 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 145.

146. Paragraph 146 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 146.

147. Paragraph 147 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 147.

148. Paragraph 148 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 148.

149. Paragraph 149 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 149.

150. Paragraph 150 states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 150.

151. Paragraph 151 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 151.

152. Paragraph 152 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 152.

153. Paragraph 153 states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 153. Amarin also denies that Plaintiff is entitled to any relief.

COUNT III
(Sherman Act Section 2 – Attempt to Monopolize)

154. Amarin incorporates its answers to Paragraphs 1 through 153 as though fully set forth herein.

155. Paragraph 155 states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 155.

156. Paragraph 156 states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 156.

157. Paragraph 157 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 157.

158. Paragraph 158 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 158.

159. Paragraph 159 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 159.

160. Paragraph 160 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 160.

161. Paragraph 161 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 161.

162. Paragraph 162 states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 162.

163. Paragraph 163 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 163.

164. Paragraph 164 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 164.

165. Paragraph 165 states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 165. Amarin also denies that Plaintiff is entitled to any relief.

COUNT IV
(The New Jersey Antitrust Act, Sections 56:9-3 and 56:9-4)

166. Amarin incorporates its answers to Paragraphs 1 through 165 as though fully set forth herein.

167. Paragraph 167 states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 167.

168. Paragraph 168 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 168.

169. Paragraph 169 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 169.

170. Paragraph 170 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 170.

171. Paragraph 171 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 171.

172. Paragraph 172 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 172.

173. Paragraph 173 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 173. Amarin also denies that Plaintiff is entitled to any relief.

COUNT V
(Common Law of the State of New Jersey – Unfair Competition)

174. Amarin incorporates its answers to Paragraphs 1 through 173 as though fully set forth herein.

175. Paragraph 175 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 175.

176. Paragraph 176 characterizes Plaintiff's claims and states legal conclusions, and therefore does not require a response. To the extent a response is required, Amarin denies the allegations in Paragraph 176. Amarin also denies that Plaintiff is entitled to any relief.

* * *

To the extent that Amarin has not responded to any allegation in the Complaint, Amarin denies such allegations and that Plaintiff is entitled to any remedy or relief. The remainder of the Complaint demands a trial by jury and recites a prayer for relief to which no response is required. To the extent that a response is required, Amarin denies that Plaintiff is entitled to any remedy or relief, including those requested.

AFFIRMATIVE DEFENSES

Amarin states the following defenses. In asserting these defenses, Amarin does not assume any burden of proof, persuasion, or production with respect to any issue where the applicable law places the burden upon Plaintiff. Amarin avers that some of the following defenses are actually elements of Plaintiff's claims on which Plaintiff bears the burden of proof, but pleads them as defenses out of an abundance of caution.

FIRST DEFENSE

The Complaint fails to state a claim upon which relief can be granted in whole or in part.

SECOND DEFENSE

The claims in the Complaint are barred, in whole or in part, because Plaintiff suffered no damage, or its alleged damages, if any, are speculative and uncertain. For the avoidance of doubt, Amarin avers that Plaintiff bears the burden of proof on these issues.

THIRD DEFENSE

The claims in the Complaint are barred, in whole or in part, because Plaintiff lacks standing, antitrust standing, antitrust injury, and injury in fact. For the avoidance of doubt, Amarin avers that Plaintiff bears the burden of proof on these issues.

FOURTH DEFENSE

The claims in the Complaint are barred, in whole or in part, because Amarin engaged in legitimate business conduct and its conduct constitutes permissible competitive activity. For the avoidance of doubt, Amarin avers that Plaintiff bears the burden of proof on these issues.

FIFTH DEFENSE

The claims in the Complaint are barred, in whole or in part, by Plaintiff's failure to mitigate damages.

SIXTH DEFENSE

The claims in the Complaint are barred, in whole or in part, because the injuries alleged by Plaintiff, to the extent any exist, were caused, in whole or in part, not by Defendants, but by acts or omissions of Plaintiff. For the avoidance of doubt, Amarin avers that Plaintiff bears the burden of proof on these issues.

SEVENTH DEFENSE

The claims in the Complaint are barred, in whole or in part, because none of Amarin's challenged actions or omissions substantially lessened competition within any properly defined market. For the avoidance of doubt, Amarin avers that Plaintiff bears the burden of proof on these issues.

EIGHTH DEFENSE

The claims in the Complaint are barred to the extent that the conduct engaged in by Amarin is immunized by the *Noerr-Pennington* Doctrine.

NINTH DEFENSE

The claims in the Complaint are barred, in whole or in part, because the challenged conduct has procompetitive justifications that outweigh any alleged anticompetitive effect. For the avoidance of doubt, Amarin avers that Plaintiff bears the burden of proof on these issues.

PRAYER FOR RELIEF

Based upon the foregoing, Amarin prays that (a) judgment be entered dismissing the Complaint on the merits, in its entirety and with prejudice, and (b) this Court grant it such other relief as it deems just and appropriate including costs and reasonable legal fees.

DEFENDANTS' DEMAND FOR JURY TRIAL

Amarin requests a trial by jury, under Fed. R. Civ. P. 38, for all issues triable of right by a jury.

Dated: April 10, 2023

s/ William C. Baton

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LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, I hereby certify that, to the best of my knowledge, the matter in controversy is the subject of three pending matters in this District: *Dr. Reddy's Laboratories Inc. v. Amarin Pharma, Inc., et al.*, Civil Action No. 21-10309 (ZNQ)(TJB); *In re Vascepa Antitrust Litigation Indirect Purchaser Plaintiffs*, Civil Action No. 21-12061 (ZNQ)(TJB); and *In re Vascepa Antitrust Litigation Direct Purchaser Plaintiffs*, Civil Action No. 21-12747 (ZNQ)(RLS). I further certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: April 10, 2023

s/ William C. Baton

William C. Baton